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K090937

510(K) Summary

E-STATIS 40 SYSTEM

JUL 24 2009

Submitted by: SciCan
1440 Don Mills Road
Toronto, Ontario Canada
M3B 3P9

Contact Person: Brenda Murphy - Director of Regulatory Affairs
(416) 446-2797

Date of Preparation: March 23, 2009

Name of Device: E-STATIS 40 Electric Motor System

Common name: Controller, Foot, Handpiece and Cord

Classification name: Dental Handpiece and Accessories

Predicate Device: **OPTIMA MX** **NuTorque**
510(k) K042759 510(k) K083252

Description of Device:

The E-STATIS type 40 Electric Motor System is designed for use in various dental procedures including dental restoration, prophylaxis and endodontics. The system is comprised of a power supply, control unit, hose and a brushless micro motor.

The control unit is equipped with five customizable endo settings including torque control, with the option of auto-stop, auto-forward and auto-reverse-forward. In addition, there are also three standard customizable operative modes. All E-STATIS components are modular and can be placed wherever the operator chooses.

The inputs to the control unit are supplied by a control panel with touch screen operation. The touch-sensitive screen has clear, user friendly symbols and provides individual selection and usage of the parameters to the individual needs of the dentist. The touch pad is removable and can be mounted either internally or externally on the dental unit.

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Intended use:

The E-STATIS type 40 dental system is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.

Technological Characteristics:

The micro motor has a rotation speed of 100 – 40000 rpm and can be rotated in a clockwise or counter clockwise direction. Performance testing was conducted to evaluate the rotational speed and torque measurements of the devices. Testing was also conducted to validate the safety and efficiency of the device, including electrical safety, electromagnetic compatibility and validation verification testing of the software.

Testing was conducted in accordance with recognized standards.

Substantial Equivalence:

Substantial equivalence was determined on the basis that the proposed device and the predicate devices were substantially equivalent in that they have the same intended use; the same operating principles; and a similar technology and design.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Brenda Murphy
Director of Regulatory Affairs
SciCan, Limited
1440 Don Mills Road
Toronto, Ontario
Canada, M3B 3P9

JUL 24 2009

Re: K090937
Trade/Device Name: E-Statix 40 System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: July 22, 2009
Received: July 23, 2009

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **E-STATIS 40 System**

Indications for Use:

The E-STATIS 40 System is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. The system provides control for motorized handpieces by converting pneumatic output from the dental treatment center to permit the operation of electrically driven dental handpieces.

Typical users of this system are trained dental professionals.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rae M. W. for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090937 SCICAN
E-STATIS 40 SYSTEM